EXHIBIT 39

Whitelaw Compliance Group, LLC.

Examination of Compliance Standards for Opioid Manufacturers and Distributors

Prepared For	Prepared By
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION *IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION* Case No. 18-OP-45132 (N.D. Ohio) MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster	Dr. Seth B. Whitelaw President & CEO Whitelaw Compliance Group, LLC. April 15, 2019

PART I: Qualifications, Scope & Methodology

1 Qualifications

For the past 30 years, I have worked in the life sciences industry as a food and drug attorney, compliance officer, compliance consultant and professor. In addition to my J.D., I have an LL.M. in Administrative Law and an S.J.D. in Health Law. Consequently, I have extensive experience working with and interpreting legislation, statutes, regulations and guidance documents.

Since 1993, I have designed, built, and run four separate corporate compliance programs for both pharmaceutical and medical device manufacturers (C.R. Bard, Inc., SmithKline Beecham Pharmaceuticals NA, GlaxoSmithKline R&D, Misonix, Inc.). I also teach monitoring and auditing to law students and working professionals, who are enrolled in Mitchell Hamline School of Law's Healthcare Compliance Certificate program.

As a consultant for Deloitte and now my own firm, I have assessed the effectiveness of numerous U.S. and international compliance programs and their ability to detect and prevent violations of the various legal, regulatory and industry standards that govern life science company operations. In addition to assessing or developing the full compliance program, I have assessed and helped develop controls in numerous discrete areas including, but not limited to:

- pharmaceutical sampling,
- payments to and services from healthcare professionals ("HCPs"),
- product diversion controls ("grey market"),
- laboratory controlled substances controls,
- promotional material claims and use,

- third-party qualification, contracting and use, and
- medical affairs unsolicited request systems.

As an in-house compliance officer, I have conducted many audits and internal investigations directed at uncovering specific misconduct by individuals at all levels of the organization. These investigations have involved sample diversion, product diversion, clinical trial fraud, bribery and corruption, theft and misuse of human biospecimens, and the falsification of domestic and international regulatory documents (submissions, reports, certifications, licenses, import/export documents, etc.).

None of the organizations reviewed in this report have employed me or engaged the services of me and my firm. For my services on this project, I am billing $400 per hour. My compensation is not dependent on my testimony or on the outcome of this case. All my opinions offered in this report are offered to a reasonable degree of certainty. Also, I reserve the right to modify or supplement my conclusions as additional information becomes available to me, or as I perform further analyses.

2 Scope & Methodology

2.1 Scope

As an expert in the design, implementation, and operation of compliance programs in the life science industry, I was retained to examine, review and discuss:

1. The relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry.[1]
2. The application of those standards to manufacturers and distributors[2] of controlled substances.
3. The effectiveness of the compliance programs for five distributors and one manufacturer of prescription opioid medicinal products based upon available documentation from 1996 to 2018 ("review period").

[1] The term pharmaceutical industry is used to encompass both pharmaceutical manufacturers ("marketing defendants") and the distributors of finished pharmaceutical products to physicians, hospitals, clinics and pharmacies ("distributor defendants").

[2] Within the pharmaceutical supply chain from manufacturer to patient, pharmaceutical distributors occupy the mid-point of the chain. Thus, at the most basic level, distributors handle the logistics of getting medicinal products from the manufacturers to the local pharmacies (including hospitals and clinics) that dispense or fill the patient's prescription obtained from a licensed prescriber (doctor, dentist, nurse practitioner, physician's assistant, etc.).

2.2 Methodology

The manufacturers and distributors of opioids (listed as Schedule II or III controlled substances) reviewed in this report can be further categorized into groups by the type of business model. As a result, there are three different groups reviewed in this report.

- Group 1 ("G1") distributors have a standard, "pure" distribution business model, which only involves distributing pharmaceutical products and providing other ancillary data and logistical services (not in the scope of this review). These distributors, McKesson, Cardinal Health and AmerisourceBergen, also are known as the "Big Three."
- The Group 2 ("G2") distributors have a standard business model that involves embedding distribution operations within a large, national pharmacy chain that supplied only its own pharmacies with opioid products. This group of distributors also utilize the G1 distributors to ensure an uninterrupted supply of opioids to their pharmacies or to handle Schedule II controlled substances. The G2 distributors examined are CVS and Walgreens.
- The Manufacturer Group produce the finished opioid products and typically sell in bulk quantities to the G1 distributors to supply retail pharmacy outlets. Mallinckrodt was sole member of this group.

Based on my experience and expertise outlined above, I can fairly evaluate the compliance controls employed by manufacturers and distributors and render opinions on whether they are aligned with regulatory requirements, expectations and leading industry practices, as well as whether they can be considered effective. My approach to this review utilized the same methodology I have used during the last 30 years when auditing or investigating compliance issues.

For all three groups in order to gain an understanding of each company's corporate compliance and anti-diversion programs during the review period, I conducted a detailed examination of both publicly available statements and documents, and documents produced by the manufacturers and distributors in the course of this case. In the course of preparing this report, that information included, but was not limited to:

- company websites and press releases;
- government enforcement settlement documents, including inspection reports, Memoranda of Agreement;
- government correspondence to and from the company;
- company policies and procedures;
- organization charts;
- reports of compliance breaches and investigations;
- compliance training materials;
- committee reports and presentation materials;
- audit and other internal review reports; and
- third party consultant reports.

That information examined was then evaluated against the standards described in Part II of this report.

I also examined relevant data showing opioid shipments as well as suspicious orders reported to the DEA by the distributors and manufacturers during the review period. This data pertained not only to Summit and Cuyahoga

Counties, but also other jurisdictions as well such as West Virginia. Although Summit and Cuyahoga Counties are the primary focus of this report, these anti-diversion programs were national programs and not state or county specific. Therefore, I have reviewed and evaluated activity that also occurred outside of Summit and Cuyahoga Counties. This is the same approach taken by the House Energy and Commerce Committee in its 2018 report.[3]

Finally, I also consulted with James Rafalski, a retired DEA diversion investigator, who also is an expert in this case. I discussed with him how the DEA applies the Controlled Substances Act, the accompanying regulations and the Agency's guidance when inspecting the controlled substances anti-diversion efforts of a manufacturer or a distributor, including their suspicious order monitoring programs. We also discussed what the DEA generally considers to constitute an effective controlled substances compliance program for a prudent registrant.

PART II: Compliance Program Standards

3 Understanding the Context

This part of the report discusses the compliance standards that pertain to the marketing, sale, and distribution of prescription opioid products. Although the focus of this report is on prescription opioid products, and with good reason given the current public health crisis,[4] most of the applicable compliance programs standards are not opioid specific. Likewise, these standards are publicly available and routinely accessed by compliance

[3] *See* U.S. House Energy & Commerce Committee Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, 115th Cong., 9 (Dec. 19, 2018) (While focused on a narrow part of West Virginia, the report raises grave concerns about practices by the distributors and the DEA nationwide.) ["W.Va. Red Flags Report"].

[4] *See* Discussion *infra* at Appendix A, Figure 1.

i. Reinstatement of disqualified or terminated customers is reviewed and approved by either the CCO or Compliance Committee.

e. Notices of customer disqualifications or terminations are communicated as soon as possible to the distributor's sales representatives.
   i. The distributor adjusts sales representative compensation plans to remove any negative impact from disqualification or termination.

3. **Manufacturer Customers**: Distributor customers of the manufacturer, which distribute the manufacturer's prescription opioid products are subject to appropriate disciplinary sanctions up to and including termination of the relationship.
   a. This requirement is explicitly stated in all customer supply contracts.
      i. Contracts contain a "for cause" immediate termination provision, which includes being non-compliant either with the manufacturer's anti-diversion requirements or when cited by the DEA.
   b. Contracts allow for the immediate cessation of chargebacks for prescription opioid products to non-compliant retail pharmacy customers.

6.7 Manufacturer – Prescriber Relationship

Opioid manufacturers within the DEA's "closed-loop" system, unlike distributors, also are uniquely positioned to observe prescriber behaviors. This occurs because the manufacturers' field forces make routine sales calls on prescribers' offices. Thus, the field forces can be exposed to some of "red flag" indicators such as overly full waiting rooms, young patients, people nodding off in the waiting room, etc.[145] Put another way, things that "if you were to walk into a doctor's office would give you pause and would make you turn around and walk out."[146] The same is true for information obtained from other sources such as IMS data, or media reports.

Given this unique vantage point, the prudent and responsible manufacturer should instruct and require its sales representatives, and in-house field support and marketing personnel, to provide any observations of potential diversionary behavior to their in-house Compliance Department for further evaluation and potential action. As Acting Administrator Rosenberg noted in the Masters Pharmaceutical proceedings, "a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices" or more specifically, "a registrant cannot claim that it … has an effective suspicious orders monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices."[147] While the company needs to act with care to be objective (which is true for every compliance investigation), "turning a blind eye" is not an option.

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[145] *See* Scott Glover and Lisa Giron, OxyContin maker closely guards its list of suspect doctors, LOS ANGELES TIMES (Aug. 11, 2013), https://www.latimes.com/local/la-xpm-2013-aug-11-la-me-rx-purdue-20130811-story html.

[146] *See id.* (quoting Robin Abrams, attorney for Purdue Pharma and a former federal prosecutor specializing in federal healthcare fraud).

[147] *See* 80 Fed. Reg. 55418, 55478 (Sept. 15, 2015).

outsourced the distribution of opioid products to their retail locations upon the reclassification of hydrocodone combination products ("HCPs") from Schedule III to Schedule II in October 2014.[151] After that date, opioid products were provided to G2 retail pharmacies via Group 1 ("G1") distributors sometimes augmented by other independent distributors serving as secondary suppliers.

Although the G2 distributors were like the G1 distributors in that profits trumped compliance, the G2 companies focused most of their anti-diversion efforts on protecting their retail pharmacy business. Consequently, the need for distribution centers to maintain reasoned, prudent and careful measures to prevent opioid diversion (e.g., a SOM program) which is expected of those handling prescription opioid medicines was treated as an afterthought, if it was recognized at all. Furthermore, distribution center anti-diversion efforts tended to focus on losses and thefts (e.g., loss prevention), rather than on whether they were shipping suspicious orders.

Again, even though applicable standards for corporate compliance and controlled substances anti-diversion programs were established in the early 1970s and 1990s respectively, it was not until the 2008-2009 timeframe that they undertook any meaningful efforts to meet their legal, regulatory and societal obligations. Nor did they make their controlled substances efforts part of their overall corporate compliance programs in a meaningful way.

The G2, for the most part, made only token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market and then only when the DEA directed them to. Thus, both companies failed to manifest good corporate responsibility by not undertaking the reasoned, prudent and careful measures expected of those handling prescription opioid products. For example, although all the G2 distributors had ready access to their own dispensing data, none of them tried to incorporate that information into their anti-diversion programs.

In addition, since retail pharmacies represent a significant profit center for the G2 group, those internally who were charged with controlled substances compliance invested substantial time and resources trying not to classify excessive pharmacy orders as "suspicious," so as not to disrupt product supply. This constituted an inherent conflict of interest that elevated profits over compliance. In short, throughout the review period, the G2 distributors failed to act responsibly to undertake the reasoned, prudent and careful measures expected of those handling prescription opioid products even while acknowledging that there was an exponential increase in opioid usage.

On the compliance maturity and program effectiveness scale, the G2 companies are barely starting into the foundational level, and while the model does not have a remedial level, if it did, that is where they would be found. Their behavior is unreasonable given the fact that they understood that (a) opioid products have a high risk of being diverted and a great propensity to cause harm when used improperly and (b) they simultaneously occupied two positions in the "closed loop" system (e.g., dispenser and distributor).

[151] *See* 79 Fed. Reg. 49661 (Aug. 22, 2014).

In July 2012, Walgreens claimed to have several policies and procedures to combat diversion.[1129] Walgreens identified those written standards as the:

- Code of Conduct,
- Controlled Substances Prescriptions and Good Faith Dispensing Policy,
- Controlled Substances Pick Up and Inventory Policies and Procedures,
- Customer Authentication Policy, and
- Handling Suspicious Drug Orders Policy.[1130]

Of those listed standards, only the Code of Conduct, Customer Authentication and Handing Suspicious Drug Orders standards applied to its Distribution Centers.[1131]

This lack of documentation not only was contrary to the requirements for credible controlled substances and corporate compliance programs, it was contrary to industry guidelines as well. HDMA, in its 2008 voluntary industry guidelines, "recommended that, to implement these Industry Compliance Guidelines, **specific written company SOPs** be developed and maintained."[1132] However, other than this single policy governing controlled substances compliance, my review uncovered nothing else resembling a policy or procedure.

The Handling Suspicious Drug Order "policy" was remarkable for its brevity and does not meet even the most basic anti-diversion requirements.[1133] It also failed to provide enough specifics to direct Walgreens staff members on what they were supposed to do.

For example, the "policy" stated that the Logistics and Planning Department sent Suspicious Order Reports to the Distribution Centers.[1134] The Distribution Centers were to file the reports for five years and make loss and theft reports to the DEA using DEA Form 106.[1135] However, beyond the generic organizational designations, the "policy" did not outline, who specifically within the Logistics and Planning Department or the Distribution Centers was responsible for ensuring Suspicious Order Reports are sent, filed, and any necessary reports made to the DEA. Nor was there any indication of who authored or approved the document.

The "policy" also did not outline the criteria the Logistics and Planning Department used to determine an order was suspicious. Key terms such as "unusual size" and "unusual frequency" were undefined in the document. It did not even incorporate the DEA regulatory requirements by reference to allow a staff member to research the DEA's definitions of those terms.

[1129] *See* Walgreens Presentation, *Walgreen Co. Controlled Substance Anti-Diversion and Compliance Program*, 5 (July 17, 2012) WAGMDL00659802.

[1130] *Id.*

[1131] *Id.*

[1132] *See* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 14 (2008) (emphasis added), WAGMDL00673706 at WAGMDL00673708.

[1133] *See* Walgreens, *Handling Suspicious Orders* (Feb. 15, 2005). The text of the policy is reproduced in Appendix G at Figure 1.

[1134] *Id.*

[1135] *See id.*